Pre-Exposure Prophylaxis (PrEP): **Lenacapavir Implementation Guidelines**

National Department of Health

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Pre-Exposure Prophylaxis (PrEP): Lenacapavir Implementation Guidelines

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Foreword

South Africa stands at a pivotal moment in strengthening its HIV prevention response. Over the past decade, the country has expanded access to biomedical tools, including nationwide oral PrEP. Yet thousands of new infections continue to occur each year, especially among adolescent girls and young women, gay, bisexual and other men who have sex with men, transgender and gender-diverse people, and other key populations. This reality highlights the need to broaden and enhance our prevention options.

The introduction of lenacapavir represents a significant advancement. As a twice-yearly injectable PrEP option, it offers a promising solution to challenges with daily adherence and supports long-term HIV prevention for those at highest risk. Its strong safety profile, robust evidence, and acceptability across diverse communities position it to contribute significantly to South Africa's prevention efforts.

These guidelines provide practical, evidence-informed direction for providers and programme teams. They outline the full spectrum of service delivery, from HIV screening and eligibility assessment to safe administration, pharmacovigilance, data management, and integration with sexual and reproductive health services, aligned with national priorities and WHO guidance.

The guidelines reaffirm the country's commitment to combination HIV prevention. The introduction of Lenacapavir expands the range of HIV prevention options that enable individuals to choose the method that best suits their needs. Ensuring equitable access, upholding user rights, and supporting informed choice remain central to our national response.

I thank the National Department of Health teams, researchers, implementing partners, clinicians, civil society, and community organisations whose collaboration has informed and strengthened these guidelines.

As lenacapavir is introduced across priority districts and facilities, these guidelines will support consistent, high-quality service delivery. Through continued partnership and commitment, we can accelerate progress toward reducing new HIV infections and safeguarding the health of our nation.

Dr SSS Buthelezi
Director-General
National Department of Health

Date:

Abbreviations and acronyms

ART	antiretroviral therapy
ARV	antiretroviral
DNA	deoxyribonucleic acid
GAHT	gender-affirming hormone therapy
GBMSM	gay, bisexual and other men who have sex with men
HBV	hepatitis B virus
HCV	hepatitis C virus
HIVST	HIV self-testing
INSTI	integrase strand transfer inhibitors
ISR	injection site reaction
LA-PrEP	long-acting pre-exposure prophylaxis
LEN	lenacapavir
NAT	nucleic acid test
NRTI	nucleoside reverse transcriptase inhibitors
NNRTI	non-nucleoside reverse transcriptase inhibitors
PEP	post-exposure prophylaxis
PrEP	pre-exposure prophylaxis
RDT	rapid diagnostic test
SAHPRA	South African Health Products Regulatory Authority
STI	sexually transmitted infection
TDF/FTC	tenofovir disoproxil fumarate/emtricitabine
WHO	World Health Organization

PART A: INTRODUCTION

1. Introduction

South Africa continues to carry one of the highest burdens of HIV globally, with approximately 7.8 million people living with HIV and thousands of new infections annually, particularly among young women, gay, bisexual, and other men who have sex with men (GBMSM), transgender and gender-diverse individuals, and key and vulnerable populations. Despite significant progress in expanding HIV prevention efforts, including widespread rollout of daily oral pre-exposure prophylaxis (PrEP), adherence challenges and stigma continue to limit uptake and sustained use.

The introduction of lenacapavir**,** a novel, long-acting injectable PrEP option administered only twice a year, offers an unprecedented opportunity to enhance choice, improve adherence, and expand HIV prevention coverage, especially for those who experience challenges with daily oral regimens.

This guideline outlines the clinical, programmatic, and operational guidance for the safe, effective, and equitable use of lenacapavir for PrEP in South Africa. It aims to support healthcare providers, programme managers, and implementers to integrate lenacapavir into HIV prevention services, aligned with national priorities and WHO recommendations.

2. Background - HIV biomedical prevention in South Africa

South Africa has led one of the world's largest and most dynamic HIV prevention programmes, with a strong focus on combination prevention that includes behaviour change, condom use, treatment as prevention, and biomedical interventions such as voluntary medical male circumcision and PrEP.

The introduction of oral PrEP in 2016 marked a critical milestone. Since then, the country has made substantial progress, with oral PrEP now offered across 97% of public primary healthcare facilities, and nearly 1.9 million PrEP initiations have been recorded by 2025. However**,** persistence with daily oral PrEP has remained a challenge, limiting its impact, especially among adolescent girls and young women (AGYW), gay, bisexual, and other men who have sex with men (GBMSM), and sex workers.

To address this, South Africa has actively explored long-acting PrEP options that overcome the barriers of daily pill burden and improve user acceptability. This includes the recent introduction of long-acting injectable cabotegravir and the upcoming introduction of lenacapavir, a 6-monthly subcutaneous injectable approved by the US Food and Drug Administration (FDA) in June 2025 and recommended for marketing authorization in the European Union by the European Medicines Agency in July 2025.

Lenacapavir represents a first-in-class capsid inhibitor with a novel mechanism of action and a long half-life, making it ideal for infrequent dosing. The pivotal PURPOSE 1[i] and PURPOSE 2 trials demonstrated near-complete protection against HIV acquisition in high-risk populations, with significantly higher adherence compared to

daily oral PrEP. These trials included adolescent girls and young women, MSM, transgender people, gender non-binary people (GNB) and pregnant and breastfeeding individuals, critical groups for South Africa's HIV prevention priorities.

This guideline leverages emerging evidence to guide the safe, equitable, and effective delivery of lenacapavir services as part of South Africa's comprehensive HIV prevention strategy.

3. Objectives and Intended Use

This guideline has been developed to provide comprehensive clinical, programmatic, and operational direction for the safe, effective, and equitable rollout of lenacapavir as a long-acting injectable option for HIV pre-exposure prophylaxis (PrEP) in South Africa. It responds to the need to expand HIV prevention choices and overcome limitations associated with daily oral PrEP, particularly for populations most at risk of HIV acquisition.

A key objective of the guideline is to support the integration of lenacapavir into South Africa's existing HIV prevention framework, including combination prevention and sexual and reproductive health (SRH) services. This integration is critical to ensure that PrEP is accessible, acceptable, and delivered as part of routine, people-centred primary healthcare.

The guideline promotes the principle of informed choice, enabling healthcare providers to present all available HIV prevention options and empower clients to make voluntary, rights-based decisions that align with their preferences and life circumstances. Standardised clinical protocols are outlined to guide providers on eligibility assessment, initiation, dosing, follow-up, missed doses, and safe discontinuation of lenacapavir.

Recognising the persistent barriers to adherence with daily oral PrEP, the guideline offers practical strategies to support long-term persistence and continuation with lenacapavir. It places particular emphasis on reaching priority populations, including adolescent girls and young women, men who have sex with men, transgender clients, and sex workers, who are disproportionately affected by HIV and may benefit most from long-acting PrEP.

Operational guidance is provided to support service delivery, facility and provider readiness, supply chain management, and pharmacovigilance. The guideline also offers tailored recommendations for the use of lenacapavir in specific populations, including adolescents, pregnant and breastfeeding individuals, and individuals with underlying health conditions or complex social contexts, such as gender-based violence or substance use.

Monitoring and evaluation are central to the implementation of lenacapavir, and the guideline identifies key indicators and data requirements to inform programme performance, ensure accountability, and drive continuous quality improvement.

Finally, this guideline supports the long-term sustainability of PrEP services by positioning lenacapavir within the broader HIV response and primary healthcare

system, thereby contributing to South Africa's universal health coverage and national HIV prevention goals.

4. Key features of lenacapavir

Table 1: Key features of lenacapavir[1]

Key features of lenacapavir	
Registered name	Lenacapavir Gilead • Lenacapavir 464 mg Solution for Injection Gilead • Lenacapavir 300 mg Tablet Gilead
Indication	For clients who perceive themselves to be at risk of acquiring HIV-1 and want to take PrEP, lenacapavir is for adults and adolescents who are HIV-negative and weigh ≥35 kg.
Description	Lenacapavir tablets: Each tablet contains 300 mg of lenacapavir. The tablets are beige, capsule-shaped, film-coated, and marked with 'GSI' on one side of the tablet and '62L' on the other side of the tablet. Lenacapavir injection: Each single-dose vial contains lenacapavir sodium equivalent to 463.5 mg of lenacapavir in 1.5 mL. The lenacapavir injectable solution is sterile, preservative-free, clear, and yellow to brown with no visible particles.
Regulatory approval	Approved by the US Food and Drug Administration for use in the USA (June 2025), European Medicines Agency (July 2025), and South African Health Products Regulatory Authority (October 2025).
Mechanism of action	Belongs to a class of ARVs called capsid inhibitors that reduce the ability of HIV to replicate at multiple essential steps in the virus's cycle. It is systemic and is absorbed throughout the body.
Schedule classification in South Africa	Classified as a Schedule 4 drug (only appropriately trained healthcare providers who are authorised to assess, diagnose, prescribe, and dispense it)
Dosage and administration	Initiation dosing includes (4 x tablets, over two days, 2 per day) and two initiation injections. Two continuation injections once every 6 months Scheduling as follows: • Day 1: 927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 x 300 mg tablets) • Day 2: 600 mg orally (2 x 300 mg tablets) • Six-monthly: 927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection, with a two-week window before or after.
Lead in period	Protection from HIV becomes effective (the drug levels reach prevention target levels or IQ4) on day three, two days after the injection, and the oral loading tablets are taken. The loading dose tablets must be taken 2 x 300 mg on day one with the injection and 2 x 300 mg on day two after the injection.

[1] Lenacapavir Gilead, Package Insert, Gilead Sciences South Africa, Approved 14 October 2025 and 21 October 2025 for Lenacapavir 300 mg Tablet Gilead and Lenacapavir 464 mg Solution for Injection Gilead respectively

Tablets	Lenacapavir tablets: Each bottle has 4 tablets, silica gel desiccant, polyester coil; white child-resistant screw cap. • Do not remove the desiccant packet. • Keep bottle tightly closed. • Store below 30ºC • Recommended excursions between 15°C – 30°C (59°F – 86°F)[2] stored at controlled room temperature, in accordance with Good Pharmacy Practice (GPP) and SAHPRA requirements.) • Dispense and store only in original container.
Injection	Lenacapavir injection: • Packaged in a dosing kit containing: ○ 2 single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL (309 mg/mL) of lenacapavir. The injection solution is sterile, preservative-free, clear, and yellow with no visible particles. Vials are sealed with a stopper and aluminum overseal with flip-off cap. ○ 2 disposable syringes, 2 withdrawal needles (18-gauge, 40mm), and 2 injection safety needles for subcutaneous injection (22-gauge, 13mm). • The vials are sealed with a rubber closure and aluminum overseal with flip off cap. • Store below 30ºC. • Store in the original outer carton in order to protect from light. • Recommended excursions between 15°C – 30°C (59°F – 86°F)[1].
Efficacy	Lenacapavir has been shown in clinical trials to be highly effective in preventing HIV acquisition among adolescents, women, pregnant and breastfeeding persons, gay, bisexual, and other men who have sex with men, as well as transgender and gender-diverse individuals. When used as directed, lenacapavir reduces the risk of HIV acquisition by at least 96%. To maintain effective protection, clients should receive their injections as scheduled to ensure consistent levels of the drug in the body. If an injection is missed or lenacapavir is discontinued, the drug levels gradually decline during a period known as the pharmacokinetic "tail." During this time, protection against HIV diminishes, and the risk of HIV acquisition increases if HIV exposure continues.
Common side effects	Most common side effects are injection site reactions (ISR) like nodules, pain erythema, swelling and induration. Other side effects include headache and nausea.

[2] Gilead Sciences, Inc. (2024). Yeztugo (lenacapavir) injection and tablets for pre-exposure prophylaxis (PrEP): U.S. Prescribing Information. Foster City, CA: U.S. Food and Drug Administration. Available from: https://www.accessdata.fda.gov

5. How lenacapavir works

Lenacapavir is a first-in-class capsid inhibitor with a novel mechanism of action, targeting HIV-1 at multiple stages of its life cycle (**Figure 1**). It interferes with three essential steps of HIV replication, namely.

- **Nuclear Transport:** It disrupts the transport of the viral capsid into the host cell nucleus, preventing the integration of viral DNA into the host genome.
- **Virus Assembly and Release:** Lenacapavir affects the assembly and release of new viral particles from infected cells, hindering the production of new virions.
- **Capsid Core Formation:** Lenacapavir interferes with the formation of the capsid core, leading to malformed capsids, which are crucial for protecting the viral RNA and enzymes necessary for replication.

It has no overlapping resistance to any currently approved antiretroviral classes and is fully active against HIV variants resistant to other antiretroviral drugs, including nucleoside reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), and integrase strand transfer inhibitors (INSTIs).

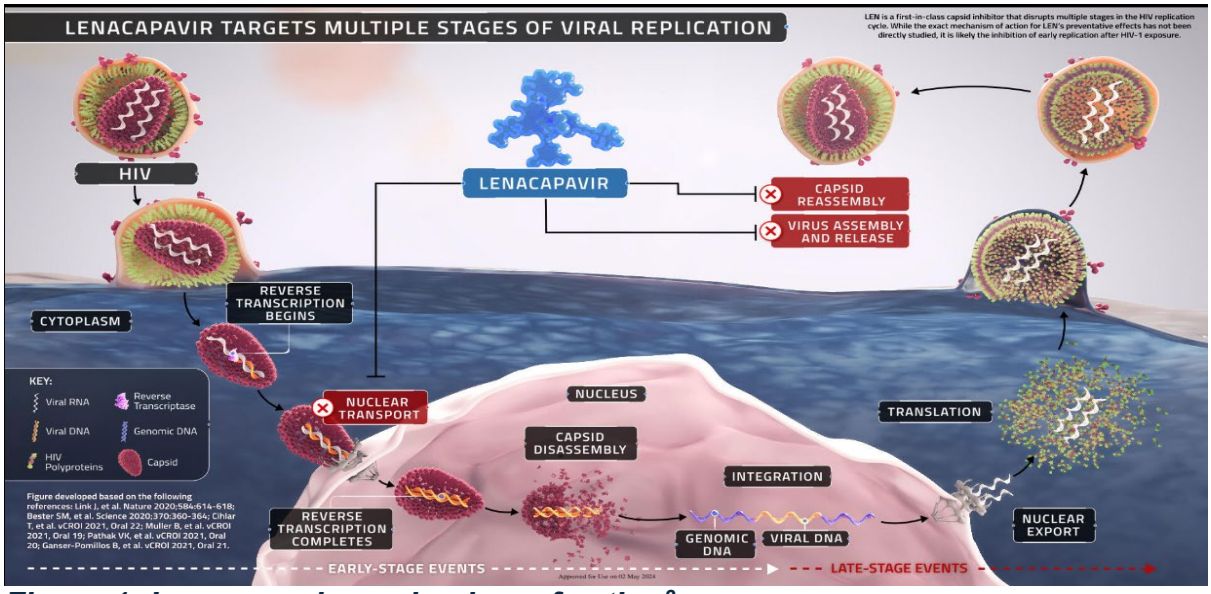

Figure 1: Lenacapavir mechanism of action[3]

[3] Gilead Sciences, Inc. (2021). *Lenacapavir targets multiple stages of viral replication* [Infographic]. Adapted from Ji et al. (2020), *Nature*; Link et al. (2020), *Nature*; Blair et al. (2021), *CROI*; O'Byrne et al. (2021), *IAS*; and Ganser-Pornillos et al. (2021), *Journal of Virology*.

PART B: CLINICAL MANAGEMENT OF LENACAPAVIR FOR PrEP

The lenacapavir initiation algorithm describes the steps to be followed for determining eligibility for lenacapavir. These are contained in **Appendix 1: Job Aid 1: Initiation Algorithm for lenacapavir**.

6. HIV screening

6.1 Ruling out HIV infection

- Perform an HIV test according to national HIV testing guidelines.
- Check for potential HIV exposure within the last 72 hours – assess for eligibility for PEP if evidence of acute HIV infection or potential exposure HIV exposure in the last 3 days.
- Screen for signs and symptoms of acute HIV infection and possible exposure within the past 28 days (**Table *2***).

Table 2 : Signs and symptoms of acute HIV infection

Signs and symptoms of acute HIV infection	
□	Fever
□	Swollen lymph glands
□	Skin rash
□	Headache
□	Sore throat
□	Aches and pain
□	Mouth sores
Note: Needs to be coupled with possible exposure to HIV, as signs or symptoms may be related to other factors. Requires clinical judgement.	

6.2 Assess and counsel for HIV prevention

- Discuss the client's interest in HIV prevention and their risk for sexual exposure to HIV. **Appendix 5: Job Aid 5: Lenacapavir Counselling guide for counsellors** can be used to make sure the important points are explained to the client
- Explore what HIV prevention methods they are using or have used in the past.
- Discuss the available HIV prevention options, including PrEP.
- Assist the client in selecting an appropriate HIV prevention option.

6.3 PrEP choice counselling

- If a client is interested in PrEP as an HIV prevention option, provide information about all the available PrEP options. These are explained in **Appendix 4 : Job Aid 4: HIV prevention product comparison table.**
- Assist client in selecting a PrEP method that aligns with their needs and preferences.
- Provide the selected PrEP method as per national guidelines

7. Assess for eligibility and screening

Should the client select lenacapavir for PrEP, provide more detailed information about lenacapavir and proceed with the following steps, using **Appendix 6: Job Aid 6: Lenacapavir counselling guide for clinicians**.

7.1 Indications and eligibility

- Adults and adolescents who want to use PrEP to reduce exposure to sexually acquired HIV, weighing ≥35kg, and who test and screen HIV-negative before initiation of lenacapavir.

7.2 Contraindications

- An HIV-positive test result according to the national HIV testing algorithm
- Individuals with unknown HIV status
- Potential exposure to HIV in the past 72 hours and not using any form of PrEP (these clients should be offered PEP)
- Signs of AHI (**Table *2***) AND potential exposure to HIV within the past 28 days
- Weight < 35kg
- Hypersensitivity to the active substance or to any of the excipients
- Co-administration with strong inducers of CYP3A, P-gp, and UGT1A1, other than rifampicin, such as:
    - anticonvulsants: carbamazepine, phenytoin
    - herbal products: St. John's wort (Hypericum perforatum)

7.3 Screening and assessment

7.3.1 Pre-initiation assessment/additional clinical screening

- STI
- Pregnancy
- Contraception
- HEP B and C (if clinically indicated)
- TB screening
- Assessment of medications and drug-drug interactions (See section 16)

7.3.2 Counselling and client information

When counselling a client about starting lenacapavir as PrEP, ensure the detailed information about lenacapavir and its use is communicated (as per **Table *3***). Confirm that the client fully understands the information shared.

Table 3: Key Counselling Messages and Client Information for Lenacapavir Use

Key Counselling Messages and Client Information for Lenacapavir Use

1. **What is lenacapavir?** Lenacapavir is a long-acting injectable medication used for HIV prevention (PrEP). It helps protect people who are HIV-negative from acquiring HIV. When taken as prescribed, lenacapavir is highly effective in preventing HIV. For optimal protection, when starting both the oral tablets and injections must be taken according to the schedule.
2. **Time to full protection:** Important to note that protection begins at day 3, i.e., after completion of the injections and the day 1 and 2 loading dose tablets are taken. The day two loading dose tablets must be taken for full protection.
3. Clients are advised to use additional prevention methods (e.g., condoms) in the first two days of commencing lenacapavir.
4. **Lenacapavir initiation** includes:
    a. Day 1:
        i. Two injections administered subcutaneously into the abdomen, thigh, back of upper arm or upper buttocks (with the second injection at least 5 centimeters from the first injection)
        ii. Two 300 mg tablets taken orally.
    b. Day 2:
        i. Two 300 mg tablets taken orally again (not to be taken on the same day as the first two tablets).
5. **Follow-up schedule:**
    a. First follow-up visit is at 4 weeks after the injection.
    b. Thereafter, injections only are given every 26 weeks (approximately every 6 months).
6. **Instructions on how to take the tablets**: Tablets must be taken as 2 tablets per day for two consecutive days; do not take all 4 tablets on the same day, as the body cannot absorb them effectively in a single dose.
7. **Possible side effects:** Most common side effect is injection site reactions such as redness, swelling, nodules, lumps or tenderness are common but usually mild and temporary. Others may include headaches, nausea, or fatigue.
8. **Lenacapavir and other medications**: Inform the provider of all medications being taken. Some drugs (e.g. strong CYP3A inducers like rifampicin and anticonvulsants) can reduce Lenacapavir levels and affect its effectiveness.
9. **Use during pregnancy:** Lenacapavir may be used during pregnancy. However, if pregnancy is planned or suspected, discuss with your healthcare provider for appropriate guidance and follow-up.
10. **Late appointments:** If you are more than 2 weeks late for your injection, additional guidance may be needed, including restarting the oral loading dose.
11. **Planned missed appointments:** If you expect to miss an appointment (e.g., travel), discuss in advance with the healthcare provider so that arrangements can be made.
12. **Stopping lenacapavir:** If you choose to stop using lenacapavir, discuss this with your healthcare provider to ensure safe discontinuation and transition to another HIV prevention method if needed.
13. **Tail period:** Lenacapavir stays in the body at low levels for over 12 months after the last injection. This period is called the "tail phase", during which there is insufficient lenacapavir in your system for protection from HIV, and you may be at risk of developing HIV resistance if exposed to the virus. Additional protection methods are recommended during this time.
14. **Emphasise combination prevention**, including:
    a. Consistent condom use
    b. STI screening and treatment
    c. Contraception to prevent unintended pregnancy
    d. Regular HIV testing

Provide the client with **Appendix 7: Job Aid 7: Lenacapavir fact sheet for clients** to take home with them so that they can read through the important lenacapavir information at their leisure.

7.3.3 Confirmation of client understanding

Before proceeding, confirm that the client understands the following key points:

- Day 1:
  - Two subcutaneous injections, either into the abdomen, thigh, back of upper arm or upper buttocks (with the second injection at least 5 centimetres from the first injection)
  - Two pills (loading dose)
- Day 2: 2 pills

  It is important that the 2 pills for Days 1 and 2 be taken on 2 separate days and not on the same day.

  If the client forgets to take the day two loading dose pills, they must take it as soon as they remember.
- Follow-up schedule includes:
  - A check-up at 4 weeks
  - Two injections every 26 weeks (6 months) thereafter
  - If injections are taken 2 weeks earlier then or after 26 weeks, then only the two injections are given (there is no need for the oral tablets.)

  Confirm that the client agrees to proceed with receiving the lenacapavir injection before administering the injection.

8. Administration of lenacapavir

8.1 Dosage and administration

For clients ≥35 kg, the dosing schedule for initiation or re-initiation consists of two subcutaneous injections of 1.5ml each and two oral tablets on Day 1, followed by two additional tablets on Day 2. The follow-up injections are repeated every 26 weeks (6-months). The detailed dosing schedule of the lenacapavir injections and the oral tablets is described in **Table *4***.

Lenacapavir is not easily absorbed from the gastrointestinal system, and so the oral loading dose must be taken as 2 x 300 mg tablets on the day of subcutaneous injection and 2 x 300 mg on the following day. These doses cannot be taken on the same day, because absorption is limited.

Table 4: Dosing schedule for lenacapavir initiation and continuation in adults and adolescents weighing ≥ 35kg[4]

Time	
Dosage of Lenacapavir Gilead: Initiation [a]	
Day 1	927 mg by subcutaneous injection (2 x 1.5 mL injections[b]) and 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)
Dosage of Lenacapavir Gilead: Continuation	
Every 6 months (26 weeks[c]) +/-2 weeks	927 mg by subcutaneous injection (2 x 1.5 mL injections)

a. The complete initiation dosing schedule, consisting of subcutaneous injections and oral tablets, is required; the efficacy of lenacapavir has only been established with this dosing schedule
b. Two injections, with the second injection at least 5 centimetres from the first injection (see Method of Administration).
c. From the date of the last injection.

8.2 Injection procedure[5]

The injection procedure for lenacapavir is outlined in **Appendix 2 : Job Aid 2: Injection procedure for** lenacapavir.
Before preparing and administering the injection, ensure that all the items listed in **Figure 2**, are available.

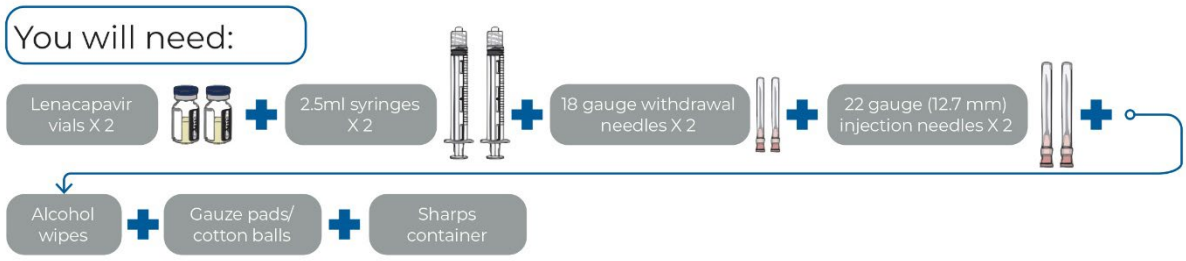

Figure 2 : Lenacapavir injection requirements

[4] Lenacapavir Gilead, Package Insert, Gilead Sciences South Africa, Approved 14 October 2025 and 21 October 2025 for Lenacapavir 300 mg Tablet Gilead and Lenacapavir 464 mg Solution for Injection Gilead respectively

8.2.1 How to inject?

Check the expiry date to make sure the product is not expired.
Visually inspect the solution in the vials and the prepared syringe for discolouration or any visible particles before administration following the steps outlined in **Figure *3***.

- Lenacapavir injection is a yellow-to-brown solution. Do not use if the solution is discolored or if it contains visible particles.
- The solution is withdrawn from the vials using an 18-gauge needle
- Change the needle to a 22-gauge 1/2 inch or 13mm needle to administer the subcutaneous injection.
- The injection should be administered as soon as possible after withdrawal from the vial.
- Do not refrigerate medication once withdrawn into a syringe.
- Any dose not administered within 2 hours of withdrawal must be discarded

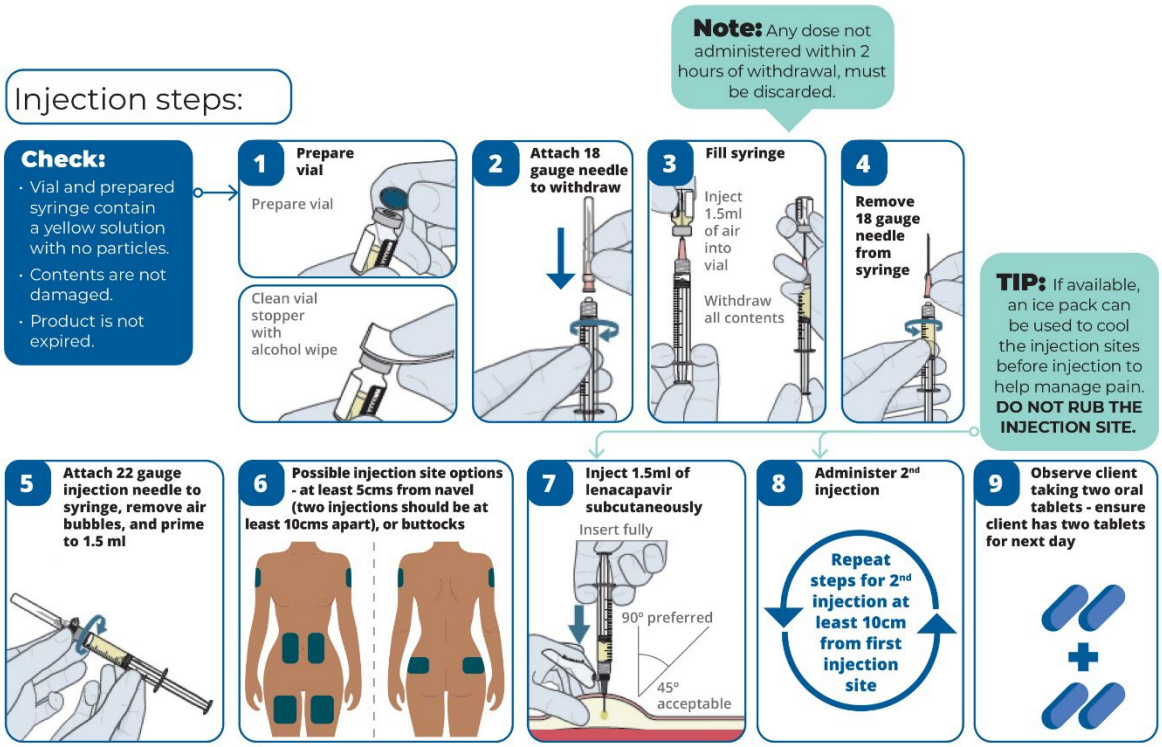

Image references: Adapted from the Package Inserts for Lenacapavir - SAHPRA, EMA and FDA.

Figure 3 : Lenacapavir injection procedure

8.2.2 Preferred subcutaneous injection sites:

The abdomen is the preferred injection site, as it provides a consistent subcutaneous layer even with high BMI.
The following alternative injection sites may also be used:

- Thigh
- Back of upper arm
- Upper buttocks

In obese clients, the abdomen remains the preferred injection site, as it provides a consistent subcutaneous layer even with high BMI.

8.2.3 To administer the injection in the abdominal area:

- Position the client on their back or seated in another comfortable position.
- Clean the two injection sites, each located at least 5 cm from the navel and at least 10 cm between the two injection sites.
- For a subcutaneous injection, the pinch-up technique is critical:
  - Pinch up a fold of skin to avoid injecting into muscle
  - Insert the needle at a 90° angle for a shorter needle (½ inch or 13mm) with a proper skin fold
  - Additional pressure may be required to administer the viscous fluid into the subcutaneous area.
- Following injection, apply gentle pressure to the puncture site with dry gauze.
- The injection will result in a subcutaneous depot which may be palpable as a nodule.

NOTE: Do not administer intradermally as this increases the risk of injection site reactions.

9. Concluding the session

Focus on the following (see key counselling points in **Table *3***):

I. Emphasise the importance of taking the second dose oral tablets (300mg x two) the day after the initial injection. Discuss practical strategies the client can use to remember this step, such as phone reminders or an alarm. Discuss possible and convenient places to safely keep the tablets until they are taken the following day. Remember to take it as soon as possible if not taken on day two.

II. Schedule a follow-up appointment one month after initiation or re-initiation to conduct an HIV test. Explain the purpose of this visit and encourage the client to prioritise attendance.

III. Provide the date of the next injection. Explain why timely injections are critical to maintain protection and explore ways the client can remember the date (e.g. SMS reminders, diary/calendar entries, or community health worker follow-up).

IV. Offer an optional interim visit for additional HIV testing and general check-in, especially if the client has concerns, experiences side effects, or requires additional support.

V. Reassure the client that they are welcome to return to the clinic at any time if they experience side effects, have questions, or need additional support.

VI. Reinforce key messages about preventing sexually transmitted infections (STIs) and the importance of contraception if required.

VII. Offer male or female condoms, water-based lubricant, as needed, and contraceptives to support comprehensive HIV, pregnancy, and STI prevention.

10. Follow-up visits

10.1 Screening tests

10.1.1 HIV test as per National HIV testing guidelines
10.1.2 Ensure that the visit is within 28 weeks since the last injection
10.1.3 If the client is late for the injection, i.e., beyond 28 weeks, follow the steps for re-initiation

10.2 Frequency of HIV testing

HIV testing and screening should be done before initiation, in one month and at each six-monthly injection visit, and more frequently if requested or clinically indicated.

10.3 Support, counselling, and monitoring

Monitor, counsel, and support clients by covering the key counselling messages ***Table* 5)** for those receiving lenacapavir during follow-up and routine visits.

Table 5 : Key counselling messages for lenacapavir follow-up visit

Key counselling messages for lenacapavir follow-up visits
1. Acknowledge and affirm the client's continued commitment to HIV prevention.
2. Create a safe space for open discussion.
3. Ask how the client is feeling since the last injection.
4. Check for any side effects, including:
a. Injection site reactions (pain, swelling, nodules)
b. General symptoms (nausea, headache, fatigue)
c. Reassure the client that most side effects are mild and temporary.
d. Refer or manage clinically significant adverse effects as appropriate.
5. Conduct an HIV test as per protocol (routine or interim visit).
6. Reassess HIV risk exposure and adherence to prevention methods.
7. Screen for STIs; offer treatment or referrals where needed.
8. Discuss contraceptive needs; provide options or referrals.
9. Offer pregnancy testing if indicated.
a. Discuss continued lenacapavir use if pregnant or planning pregnancy.
10. Provide condoms and water-based lubricant where required.
11. Confirm the next injection date (every 26 weeks / 6 months).
12. Emphasise:
a. Importance of on-time injections to maintain protection.
b. Use of reminders (SMS, appointment card, digital calendar).
13. What to do if they miss or are late for their appointment.
14. If the client is considering stopping lenacapavir:
a. Explain the 12-month tail period where drug levels persist but may not be protective.
b. Discuss risks of HIV resistance if exposed during this time.
c. Offer alternative PrEP or combination prevention strategies.
d. Reinforce need for ongoing HIV testing and condom use during this period.
15. Ask about any new medications started since the last visit.
16. Screen for any new medical conditions or recent hospitalisations.
17. Assess for potential drug interactions or clinical concerns.
18. Reiterate the effectiveness of combination prevention:
19. PrEP + condoms + STI treatment + contraception
20. Empower the client with knowledge and agency in their HIV prevention journey.

21. Allow time for discussing questions or concerns.
22. Confirm that the client:
    a. Knows when to return
    b. Understands what to do in case of side effects
    c. If late or missed the next injection visit
    d. Feels supported in their prevention plan
23. Close with encouragement and appreciation.

11. Delayed and missed doses

11.1 Management of missed dose of lenacapavir tablet

If the day 2 oral loading dose of 2 x 300mg tablets is missed, take it as soon as possible. Do not take Day 1 and Day 2 oral initiation doses on the same day. Remind the client to use additional protection until the day after the second oral loading dose is taken.

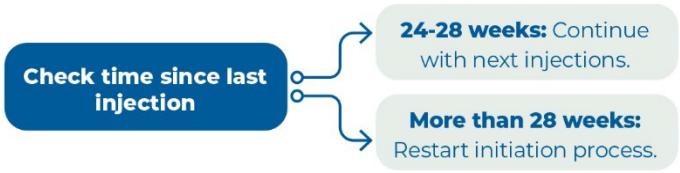

Figure 4 : Delayed and missed injections

11.2 Missed Injections

If a client has missed their scheduled visit by more than two weeks (more than 28 weeks since their last injection (**Figure 4**), the following should be done:

11.2.1 Assess whether the use of lenacapavir is still the preferred option
11.2.2 Counsel on the importance of returning for injection appointments
11.2.3 Reinitiate with the initiation dosing schedule from Days 1 and 2 (**Table 1**) that includes the oral loading dose tablets on Days 1 and 2 and then continue with continuation injection dosing schedule.

12. Re-initiation

1. Conduct an HIV test: follow the South African HTS guidelines
2. Rule out HIV infection
3. Check for potential HIV exposure within the last 72 hours – assess for eligibility for PEP
4. Screen for symptoms of acute HIV infection and possible exposure within the past 28 days

For re-initiating a client, follow the initiation process outlined in sections 6, 0, and 8.

13. Stopping lenacapavir

Stopping lenacapavir may be planned or may occur inadvertently if a client does not return for their scheduled injection. The possibility of stopping should be discussed during the initiation visit and revisited at every continuation visit, ensuring that clients are informed about the implications and supported in making informed decisions.

If a client decides to stop using lenacapavir, the concentration of lenacapavir declines and falls below the protective threshold level 28 weeks after the last dose. Twenty-eight weeks after the last lenacapavir injection, the drug remains in the body but at levels that may not provide effective HIV prevention. This is referred to as the "tail period", which could last 12 months or longer after the last dose. Missed doses could lead to the acquisition of HIV and possibly the development of resistance in the acquired HIV to lenacapavir. As with all PrEP methods, if a client discontinues lenacapavir and is at continued risk of HIV exposure, they should be encouraged to transition to another PrEP method or use another effective HIV prevention strategy during the tail period and testing at least 3-monthly over the next year.

13.1 Key counselling points to discuss regarding discontinuation:

Table 6: Key counselling messages for discontinuation of lenacapavir

Key counselling messages for discontinuation of lenacapavir
1. Lenacapavir remains in the body for 12 months or more after the last injection, but at decreasing levels insufficient to provide protection from HIV acquisition. 2. There is the possibility that if the client acquires HIV, there may also be lenacapavir drug resistance in the acquired HIV. 3. It is important to use alternative prevention strategies, such as alternative PrEP methods or condoms if there is a possibility of continued exposure to HIV. 4. Three-monthly HIV testing is recommended. 5. Encourage continued use of SRH services, including STI prevention and contraception. 6. Provide information about post-exposure prophylaxis. **Use Appendix 3 : Job Aid 3: Stopping lenacapavir and switching between prevention methods** to make sure that you explain the important points regarding stopping lenacapavir.

14. Switching between PrEP methods

Clients may choose to switch between PrEP methods, depending on the methods available. The simultaneous use of different PrEP methods is not recommended.

Use Appendix 3 : Job Aid 3: Stopping lenacapavir and switching between prevention methods to discuss the key point regarding switching between PrEP methods.

14.1 Switching from lenacapavir to oral PrEP:
A client may switch from lenacapavir to oral PrEP after 26 weeks and a negative HIV test result. Protection is maintained if the oral PrEP is commenced before 27 weeks. If the client switches to oral PrEP after 27 weeks since the last lenacapavir injection, they will require at least 7 days of oral PrEP before full protection from HIV is attained. (follow oral PrEP initiation guidelines)

14.2 Switching from oral PrEP to lenacapavir:
Commence lenacapavir injections on the day oral PrEP is stopped or any day thereafter. The two lenacapavir injections are followed by two doses of oral lenacapavir on the day of the injection and 2 tablets the day after. The client must be informed about the need for additional protection from HIV until the day after the second two oral tablets are taken.

14.3 Lenacapavir and PEP:
PEP will only be required if there is a possible exposure to HIV after 28 weeks since the last lenacapavir injection. (Offer PEP as per national guidelines).

14.4 PEP to lenacapavir:
Lenacapavir can be commenced after 28 days of PEP and HIV-negative test result.

14.5 PrEP and condoms:
PrEP and condoms can be used simultaneously, and clients are encouraged to use condoms for additional protection.

15. Common side effects

The most side effects for lenacapavir experienced by were injection site reactions (ISR). These reactions at the injection site may include site nodule, pain, induration, erythema, swelling, pruritus, bruising,
warmth, discolouration, oedema, ulcer, haematoma, haemorrhage, and discomfort.
Most nodules can be felt but not seen, are small and resolve over time.
More severe ISR e.g. skin damage, or ulcers were rare.
Some users experienced headaches, nausea, dizziness, vomiting and diarrhoea.
Improper administration (intradermal) has been associated with serious injection site reactions, including necrosis and ulcer; therefore, it is important to ensure injection is only administered subcutaneously.

16. Lenacapavir and drug interactions

Lenacapavir is metabolised by the isoenzyme CYP3A and through the glucuronidation (UGT system) and is cleared mostly by the biliary route. This means that its metabolism rate can be affected by other drugs that strongly or moderately induce or speed up the action of the CYP3A system. Lenacapavir is, however also a moderate inhibitor of CYP3A in its own right. Lenacapavir's blood levels can therefore be affected by certain drugs if taken concomitantly, and lenacapavir can affect the levels of some other drugs in the blood if used at the same time.
Drugs that are inducers or inhibitors of the CYP3A and UGT may determine variations in the levels of lenacapavir in plasma. It is therefore important to know whether concomitant medications are needed or are being taken by the PrEP user.

16.1 If LEN is given with CYP3A inducers (see examples below):

When lenacapavir is co-administered with CYP3A inducers, its clearance from the body increases (**Figure *5***), potentially lowering plasma concentrations below the level required for effective HIV prevention.

On the other hand, when using lenacapavir for PrEP (which is an inducer of CYP3A) with drugs that are themselves sensitive substrates for CYP3A metabolism, eg PDE5 inhibitors (used for erectile dysfunction) or statins, the administration of lenacapavir can increase the blood levels of those drugs potentially leading to side effects or toxicity.

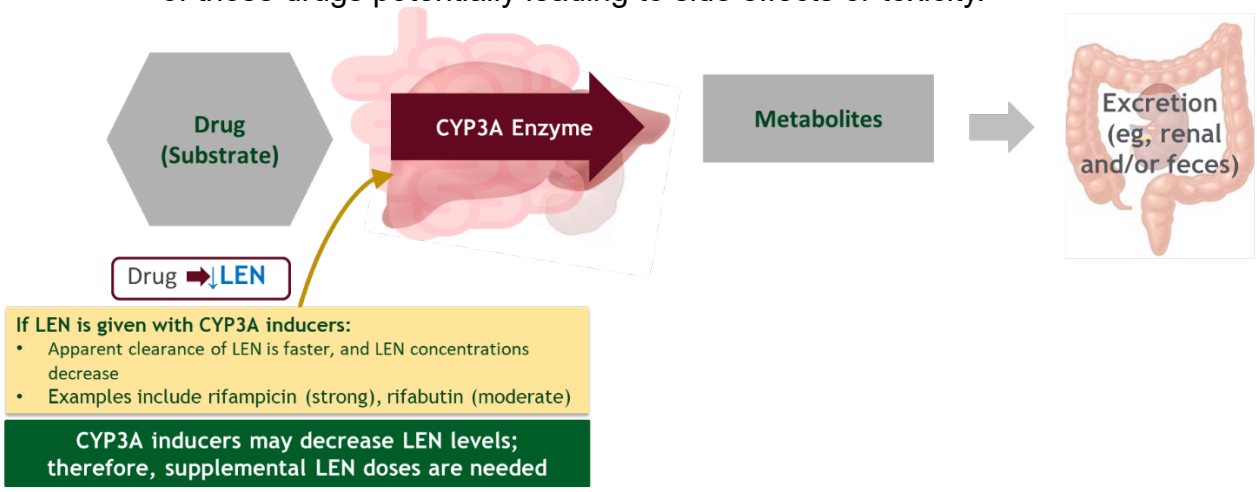

Figure *5* : Effect of lenacapavir co-administered with drugs that are CYP3A inducers or CYP3A substrates[6]

Concomitant administration of lenacapavir with strong inducers of CYP3A, P-gp, and UGT1A1, other than rifampicin, is therefore contraindicated.

Dose adjustment of lenacapavir is required if rifampicin is co-administered

6

(see
Table 7). It is NOT recommended to initiate a strong CYP3A inducer, e.g. Rifampicin before administering lenacapavir.

If lenacapavir is discontinued, residual concentrations of lenacapavir may remain in the systemic circulation of individuals for prolonged periods. These concentrations may affect the exposures of other drugs medicines (i.e. sensitive CYP3A and/or P-gp substrates) that are initiated within 9 months after the last subcutaneous dose of lenacapavir.

Strong inhibitors of CYP3A, P-gp and UGT1A1 together (i.e., all 3 pathways) may significantly increase plasma concentrations of lenacapavir, therefore co-administration is not recommended.
Other examples of strong CYP3A isoenzyme inducers are:

- Carbamazepine (for epilepsy)
- Phenytoin (for epilepsy)
- Phenobarbital (for seizures)
- St. John's Wort (herbal supplement)

**Supplemental doses of lenacapavir are recommended for clients initiating rifampicin therapy (refer to
Table 7).**

Rifampicin may be initiated starting at least 2 days after lenacapavir is first initiated (**Figure *6***).

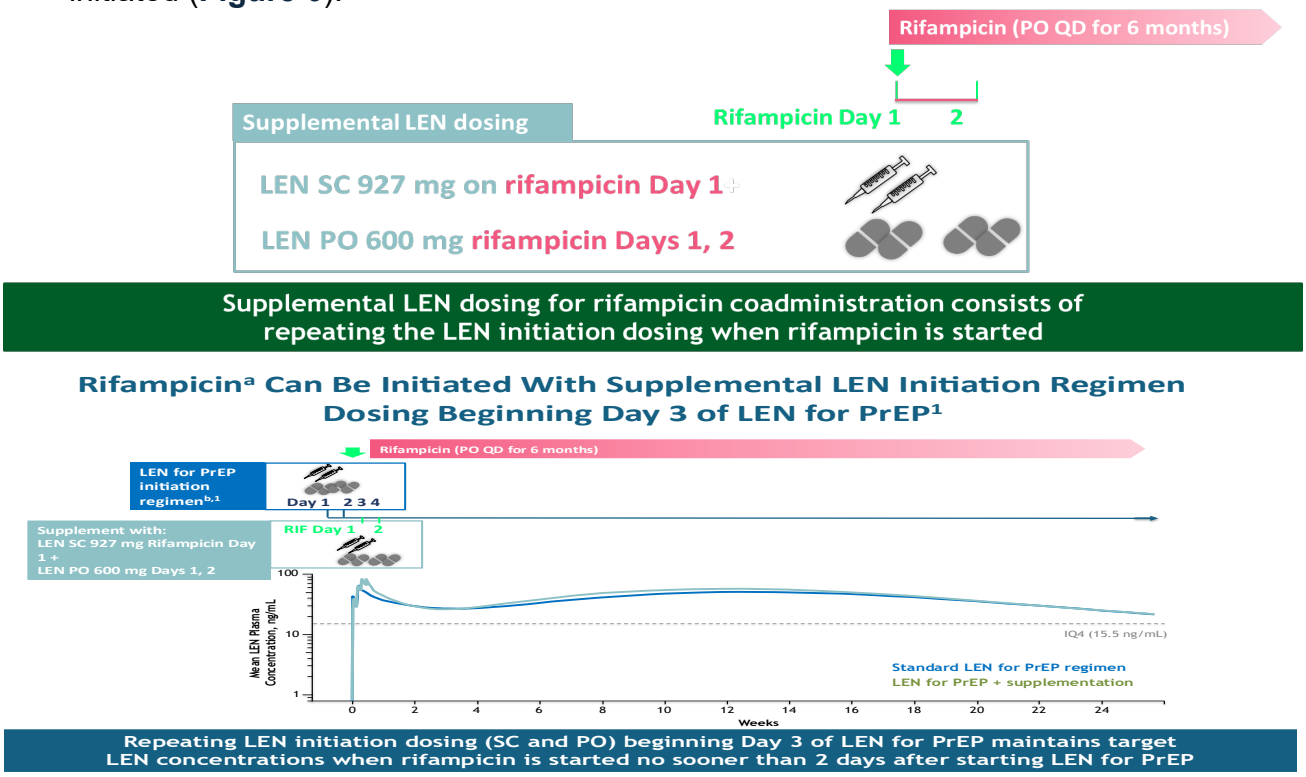

Figure *6* : Supplemental lenacapavir dosing schedule with coadministration of rifampicin[7]

[7] Bekker et al presentation at 13th International Aids Society (IAS) conference on HIV Science 2025, July 13-17, 2025, Kigali, Rwanda.

Table 7: Supplemental dosing recommendations for clients on lenacapavir initiating rifampicin

Medicinal Product	Recommendation concerning coadministration with lenacapavir

Rifampicin	If rifampicin is co-administered, maintain the usual lenacapavir dosing schedule and administer additional doses of lenacapavir as follows:
	• In individuals receiving lenacapavir, rifampicin may be co-administered **starting at least 2 days after lenacapavir is first initiated.**
	• **On the day rifampicin is initiated**, administer:
	  ○ 927 mg of lenacapavir subcutaneously (2 x 1,5 ml injections) and
	  ○ 600 mg of lenacapavir orally (2 x 300 mg tablets)
	• **On the day after rifampicin initiation,** administer:
	  ○ 600 mg of lenacapavir orally (2 x 300 mg tablets)
	• If rifampicin is co-administered for longer than 6 months, continue to administer additional doses of lenacapavir as described above, every 6 months following the day of rifampicin initiation
	• After stopping rifampicin, maintain the usual lenacapavir dosing schedule

16.3 Moderate CYP3A Inducers

These may also reduce lenacapavir plasma concentrations but to a lesser extent. Examples include:

- Rifabutin (TB treatment)
- Modafinil (used for sleep disorders)
- Bosentan (used for pulmonary hypertension)
- Nafcillin (antibiotic)

Concomitant administration of lenacapavir with moderate inducers of CYP3A and P-gp, other than rifabutin, is therefore not recommended.

Supplemental doses of lenacapavir are recommended for clients initiating therapy with rifabutin (**Figure 7**).

Rifabutin may be initiated at any time after lenacapavir is first administered

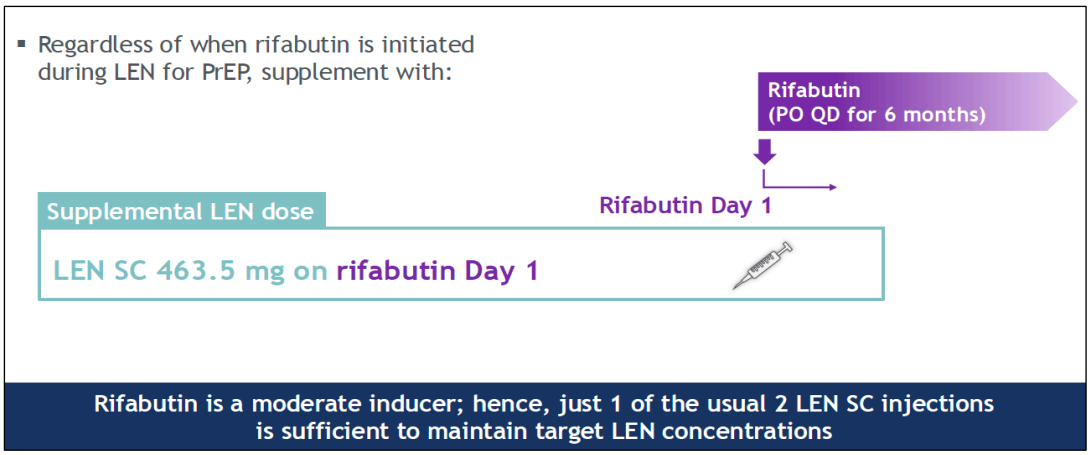

Figure 7: Supplemental lenacapavir dose with rifabutin[8]

Table 8: Dosing recommendations for individuals receiving lenacapavir and initiating therapy with rifabutin

Medicinal Product	Recommendation concerning coadministration with lenacapavir
Rifabutin	If rifabutin is co-administered, maintain the usual lenacapavir dosing schedule and administer additional doses of lenacapavir as follows: • **On the day rifabutin is initiated**, administer 463,5 mg of lenacapavir subcutaneously (1 x 1,5 ml injection) • If rifabutin is **co-administered for longer than 6 months**, continue to **administer additional doses of lenacapavir as described above**, every 6 months following the day of rifabutin initiation.

Concomitant administration with rifapentine is not recommended.

When using Len for PrEP (which is an inducer of CYP3A) with drugs that are themselves sensitive substrates for CYP3A metabolism, e.g. PDE5 inhibitors (used for erectile dysfunction) or statins, then it is important to start those drugs at a low dose and titrate the dose gradually whilst carefully monitoring both the therapeutic effect and side effects.

[8] Bekker et al presentation at 13th International Aids Society (IAS) conference on HIV Science 2025, July 13-17, 2025, Kigali, Rwanda.

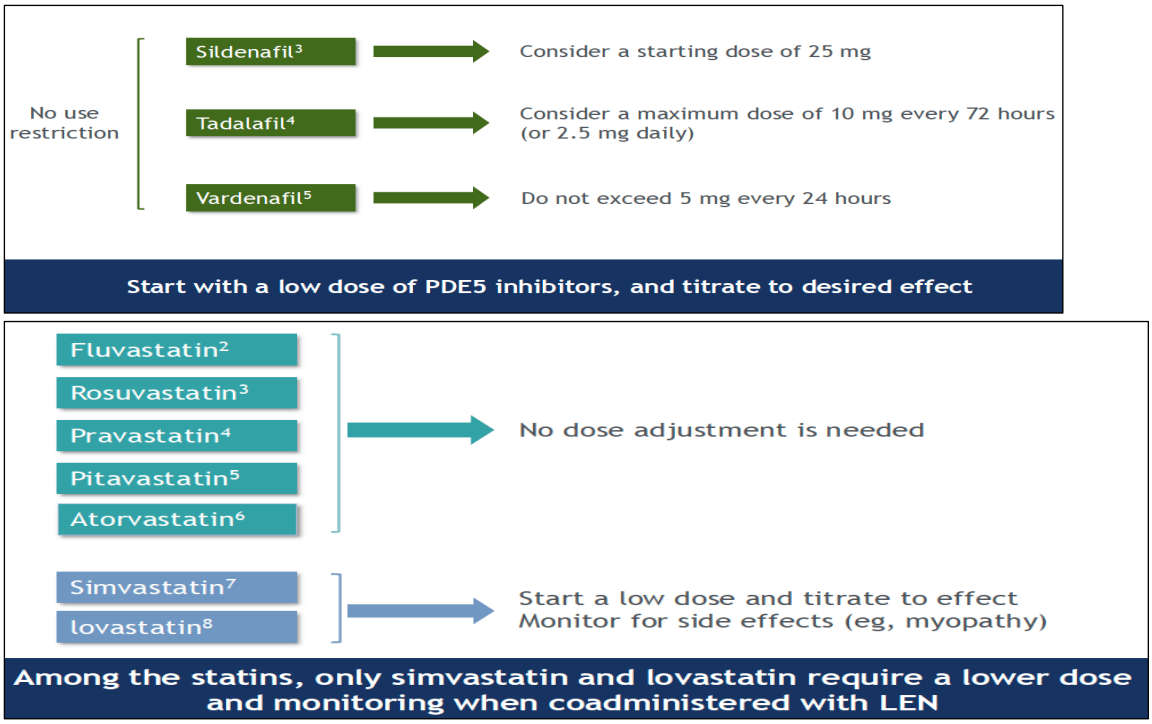

Figure *8*: Co-administration of lenacapavir with PDE5 and HMG-CoA Reductase inhibitors[9]

16.2 Key points for clinicians

When using lenacapavir

- Strong CYP3A inducers, other than rifampicin, is contraindicated
- Moderate inducers of CYP3A and P-gp, other than rifabutin, are not recommended.
- Supplemental doses of lenacapavir are recommended for clients initiating therapy with rifampicin and rifabutin (see Table 7 and 8)
- Always check for interactions before starting or stopping any medication.
- Always check for possible interactions[10] if the client is on concomitant chronic medications.

17. Special considerations

17.1 Pregnant and Breastfeeding Women

- Lenacapavir is considered safe based on current data for pregnant and breastfeeding persons. Available pregnancy outcomes were similar to those expected for the general population.
- No specific safety concerns have been reported.
- Provide risk-benefit counselling before initiation.
- Monitor the pregnancy through a pregnancy registry and complete the **Appendix 9: PrEP Pregnancy Outcome Form** post-delivery for any

[9] Bekker et al presentation at 13th International Aids Society (IAS) conference on HIV Science 2025, July 13-17, 2025, Kigali, Rwanda.
[10] https://www.hiv-druginteractions.org

person who was exposed to PrEP drugs at any time during their pregnancy
- For pregnant women, consider one of the alternate injection sites if preferred, especially in the second and third trimesters when the skin of the abdomen is taut.

17.2 Adolescents (≥35 kg)
- Lenacapavir is approved for use in adolescents who weigh 35 kg or more.
- Dosing is the same as for adults.
- Plasma concentration in adolescents and adults is comparable
- Adverse reactions in adolescents were consistent with those in adults.

17.3 Older Adults (over 50 years of age)
- Not enough older adults were included in studies to confirm safety.
- Use with caution, especially if the client has:
  - Liver, kidney, or heart problems
  - Multiple other medicines or health conditions

17.4 Renal (Kidney) Impairment
- No dose adjustment needed in:
  - Mild, moderate, or severe kidney problems (CrCl ≥15 mL/min)
- Not studied in people with end-stage kidney disease (CrCl <15 mL/min) or on renal replacement therapy therefore, lenacapavir should be used with caution in these individuals.

17.5 Liver (Hepatic) Impairment
- No dose adjustment is needed in mild (Child-Pugh A) or moderate (Child-Pugh B) liver impairment
- Lenacapavir has not been studied in individuals with severe liver disease (Child-Pugh C), therefore it should be used with caution in these individuals.

17.6 Gender-Based Violence (GBV) and Intimate Partner Violence (IPV)
- Offer confidential GBV/IPV screening and referral services.
- Ensure women and adolescents can make safe and informed PrEP choices.

17.7 People Who Use Drugs or Inject Drugs
- There is insufficient evidence for injectable drug users.
- Support safe use through harm reduction services and counselling on parenteral HIV risks.

18 Management of HIV seroconversion

Refer all persons who have an HIV positive test result for immediate first-line HIV treatment. Inform the healthcare provider of lenacapavir use and the circumstances of seroconversion. In addition, complete the **Appendix 10: PrEP Seroconversion Form**.

The risk of seroconversion with regular 6-monthly injections is very unlikely. Six months after the last injection, residual volumes of lenacapavir may remain in the system for a period of at least 12 months.
Post-marketing surveillance will be required to obtain further evidence regarding breakthrough seroconversions and potential lenacapavir drug resistance.

19 Monitoring and reporting

Routine monitoring of the lenacapavir implementation is essential to monitor, evaluate, and learn more about the implementation of this new PrEP product. The data collected will also assist with forecasting demand to ensure a sufficient and uninterrupted supply of lenacapavir.

19.1 Recording and reporting

To facilitate standardised and systematic monitoring of the programme, all PrEP service points must use the updated National Department of Health's **Appendix 8: PrEP Clinical Form** to collect client data. PrEP providers must ensure that the form is completed in detail and kept in the client's file at the healthcare facility. Use the information recorded on the clinical form to capture the data elements outlined in **Table *9*** onto TIER.Net after each clinical visit or if there is a change in the client's status as a PrEP user.

Table 9 : Lenacapavir data elements

Data elements	Definition	Source document	Point of collection
Lenacapavir initiation	Number of individuals (disaggregated by age) who receive lenacapavir for the first time in the reporting period.	PrEP Clinical Form	At lenacapavir initiation
Continuation on lenacapavir	Number of individuals (disaggregated by age), inclusive of those newly enrolled, that received lenacapavir in the reporting period.	PrEP Clinical Form	At scheduled follow-up visit
Switch to Lenacapavir	Number of individuals (disaggregated by age), inclusive of those newly enrolled, that switched to lenacapavir in the reporting period.	PrEP Clinical Form	At scheduled follow-up or a restart visit

19.2 Reporting of adverse events

Reporting suspected adverse reactions is important. It allows further monitoring and analysis of the adverse events. Suspected adverse reactions need to be recorded in the client's clinical record and reported to SAHPRA via the *6.04 Adverse Drug Reactions Reporting Form.* This can be found on the following link: https://www.sahpra.org.za/Publications/Index/8

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Gilead Sciences South Africa (Pty) Ltd. Package Insert: Lenacapavir 300 mg Tablet Gilead. 300 mg film-coated tablets. Approved by the South African Health Products Regulatory Authority on 14 October 2025 and supplied by Gilead Sciences, South Africa

Gilead Sciences South Africa (Pty) Ltd. Package Insert: Lenacapavir 464 mg Solution for Injection. Approved by the South African Health Products Regulatory Authority on 21 October 2025 and supplied by Gilead Sciences, South Africa

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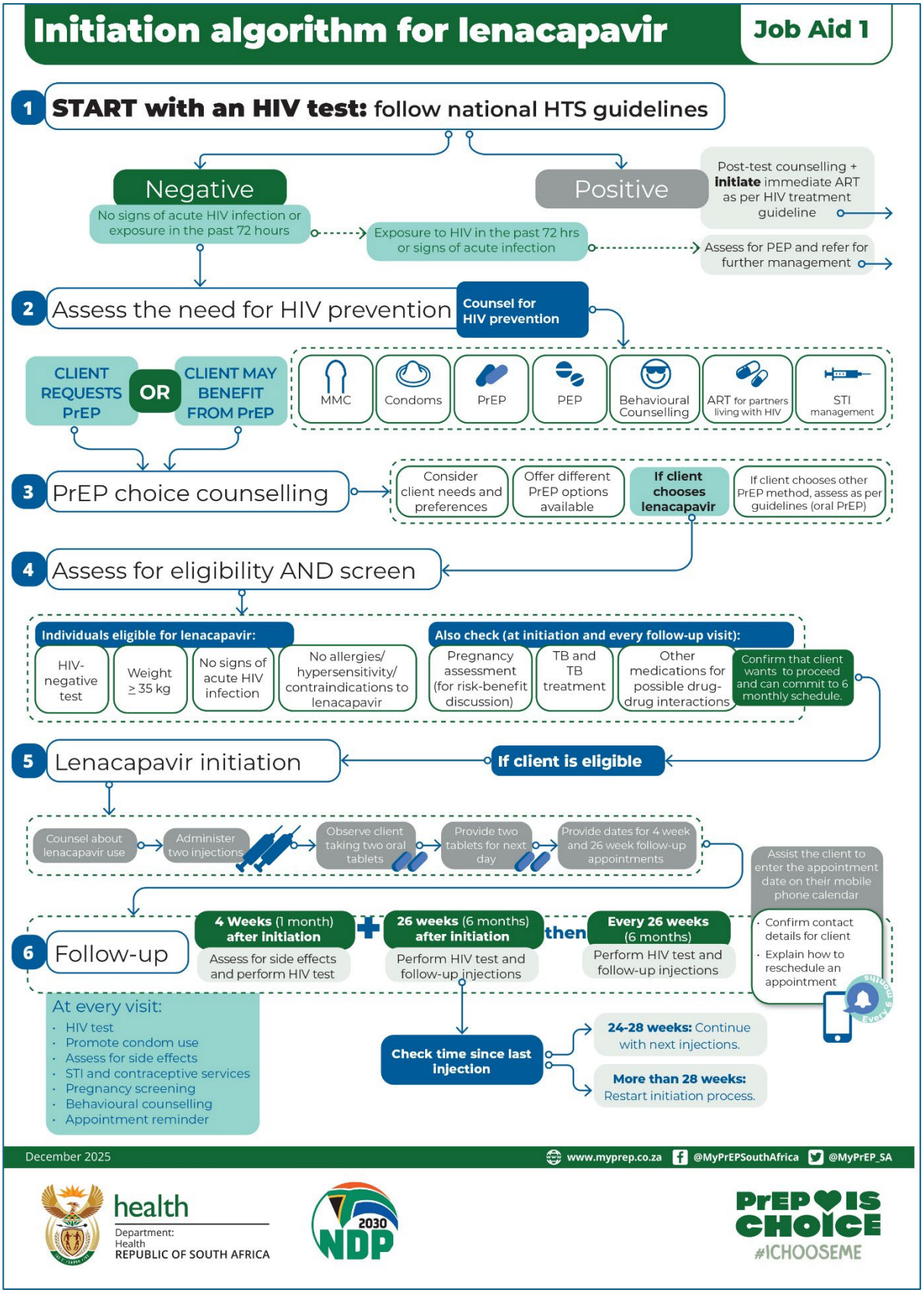
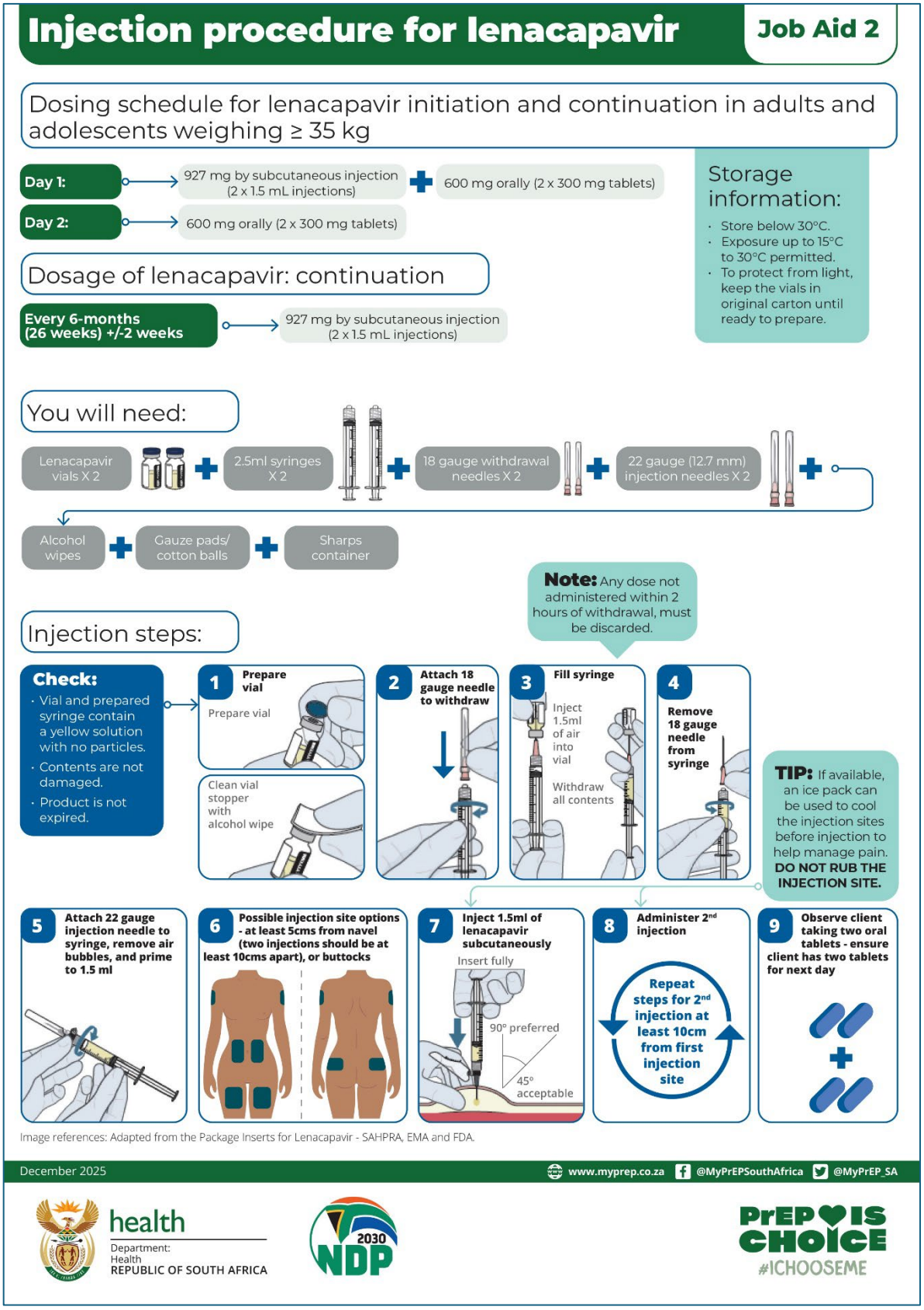
Appendices

Appendix 1: Job Aid 1: Initiation Algorithm for lenacapavir



Appendix 2 : Job Aid 2: Injection procedure for lenacapavir



Appendix 3 : Job Aid 3: Stopping lenacapavir and switching between prevention methods

Stopping lenacapavir and switching between prevention methods

Job Aid 3

If a client wants to stop, explain the following:

- After the last injections, the client remains protected for 6 months.
- After 6 months, the drug level gradually decreases, thereby reducing the level of HIV prevention.
- It takes about 1 year after stopping for lenacapavir to clear from the body.
- During this time, if a client contracts HIV after stopping lenacapavir, they may develop resistance to ARVs if exposed to HIV.
- After stopping lenacapavir, it's important to use other HIV prevention methods (oral PrEP or condoms) if there's ongoing potential for exposure to HIV.

Switching between PrEP methods:

Clients may choose to switch between PrEP methods, and the process will vary depending on the method. Each option should be provided in line with current South African guidelines, using clinical judgement as outlined below.

Oral PrEP → LEN	Stop oral PrEP and initiate LEN as soon as possible or any time after. Advise client to use other prevention tools (condoms) for the first two days from initiation.
LEN → Oral PrEP	The last injections provides protection for six months, so it would only be necessary to initiate oral PrEP after the six months have passed.
PEP → LEN	Complete 28-day course of PEP, as per guidelines. Initiate LEN after an HIV-negative test result.
LEN → PEP	PEP is not required while the client is on the scheduled LEN regimen, only if the person had a potential exposure to HIV after stopping LEN (six months after last injections).

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Appendix 4 : Job Aid 4: HIV prevention product comparison table

HIV prevention product comparison table

Job Aid 4

	Oral PrEP	LEN	Condoms	PEP
Active ingredients	Tenofovir and Emtricitabine (TDF/FTC)	Lenacapavir	No active ingredient	TDF / 3TC / DTG once daily as TLD
Description	Single-dose tablet	Each vial contains 463.5 mg and each oral tablet contains 300mg.	External – thin rubber (latex); Internal – soft plastic (nitrile)	Single-dose tablet
How is it given?	Tablet – taken orally daily	At initiation, two subcutaneous injections and two oral tablets taken on day 1, and two oral tablets taken on day 2. Thereafter, two subcutaneous injections given ever 26 weeks (every 6 months)	External condom worn on penis (optional use of water-based lubricants if preferred); internal condom inserted into vagina	Tablet – taken daily (oral) for 28 days
How does it work?	Antiretroviral drugs (TDF/FTC) prevent HIV from replicating. Oral PrEP works systemically, so the drug is absorbed throughout the body and provides protection from HIV throughout the body.	An antiretroviral drug (lenacapavir) is slowly released into the blood stream after receiving the injections and taking the tablets, reducing the ability of HIV to replicate itself inside a healthy cell. Delivered systemically, the drug is absorbed throughout the body and provides prevention against HIV throughout the body.	Provides a strong barrier to prevent the virus from entering the body – for anal, oral and vaginal sex. Needs to be used for each sex act.	PEP uses antiretroviral drugs (TDF/FTC plus an integrase inhibitor like dolutegravir or raltegravir) to stop HIV from establishing infection after exposure. It works by blocking the virus from replicating and integrating into the body's DNA, preventing it from taking hold.
Who is it for?	Individuals with an HIV-negative test result weighing 30 kg and more; willing to use oral PrEP correctly as prescribed for protection against all exposure to HIV, and according to guidelines and eligibility.	Individuals with an HIV-negative test result weighing 35 kg and more; willing to return for injection appointments for protection against all exposure to HIV, and according to guidelines and eligibility.	Anyone wanting protection against HIV, STIs and pregnancy.	Individuals with an HIV-negative test result who were potentially exposed to HIV within the past 72 hours (3 days), according to guidelines and eligibility.
Frequency?	Daily pill	Every 26 weeks (6-monthly)	Each time a person has sex	Daily pill for 28 days
Privacy/ Discretion?	Pills and pill bottles are visible, use can be concealed, if needed.	Very private. Nodules at the injection sites after injections may be palpable.	Not private. Requires both partners to agree to its use.	Pills and pill bottles are visible, use can be concealed, if needed.
Availability?	Available at many public health facilities, institutions of higher learning and project sites.	Subject to approval by NEMLC for inclusion into the essential medicines list (EML).	Available free at all clinics, some public venues, and for sale at varied prices from shops and other outlets.	Available at most public health facilities.
Efficacy?	Over 90% Highly effective	Over 96% Highly effective	Highly effective when used correctly, also protects against STIs and unintended pregnancy.	PEP reduces the risk of HIV infection by over 80%, possibly higher if taken within 24 hours of exposure and for 28 days.

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Appendix 5: Job Aid 5: Lenacapavir Counselling guide for counsellors

Counselling guide for COUNSELLORS

Job Aid 5

FRONT

PrEP (Pre-Exposure Prophylaxis) Counselling Guide for Counsellors

Step 1: HIV testing and counselling:

Pre-test information → HIV test → Post-test counselling

For clients who test negative for HIV:

Step 2: Assess your client's need for PrEP

be sensitive and non-judgmental

With sensitivity, explore with your client their possible exposure to HIV, this includes asking:

- Do you ever have sex without using a condom?
- Do you ever have sex while using alcohol and/or drugs?
- Do you ever have sex with partner/s whose HIV status is unknown?
- Do you have sex with partner/s living with HIV, without using a condom?

Individuals who answer YES to any of these questions or **ask for PrEP** should be considered for PrEP.

Step 3: Inform your client about PrEP, that it prevents HIV, and is available at this clinic.

always try to use a condom as well as PrEP

- PrEP is an ARV pill or injection used to PREVENT HIV infection.
- PrEP is taken **before** a person comes into contact with HIV.
- PrEP is for people who test negative for HIV.
- The PrEP pill is taken daily for as long as you need it, while the PrEP injection is given every 6 months.
- PrEP is safe and highly effective, even if you are pregnant and/or breastfeeding!

Your client can use the PrEP method quiz to find a method that could work for them

Step 4: Find out if your client is interested in knowing more about PrEP, and which method they are interested in.

Step 5: If your client is interested in PrEP, inform them that the nurse will complete additional health checks.

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Counselling guide for COUNSELLORS

Job Aid 5

(Continued)

BACK

More about oral PrEP

Oral PrEP is a pill containing antiretroviral medication (ARVs), taken by HIV-negative people to prevent getting HIV.

- **Oral PrEP is a daily pill taken to prevent HIV.**
- **Oral PrEP is safe to use!**
- **Oral PrEP contains two antiretroviral ingredients called tenofovir and emtricitabine that work together to prevent HIV.**

When taken every day, oral PrEP can reduce the likelihood of getting HIV by more than 90%.

More about injectable PrEP

LENACAPAVIR (LEN) or injectable PrEP is a 6-monthly HIV prevention option, it is for people who test negative for HIV

- **LEN is six-monthly injections given to prevent HIV.**
- **LEN is safe to use!**
- **LEN contains an antiretroviral ingredient called lenacapavir which is injected on the stomach area or thighs.**

LEN is **more than 96% effective** in preventing HIV if it is used as prescribed!

WHO CAN USE Oral PrEP?
Any person who has an HIV-negative test result and weighs 30kg or more.

WHO CAN USE LEN?
Any person who has an HIV-negative test result and weighs 35kg or more.

HOW DOES Oral PrEP PREVENT HIV?
If a person is HIV-negative, the medication in oral PrEP protects the cells in the body from being infected with HIV.

HOW DOES LEN PREVENT HIV?
Lenacapavir is slowly released into the bloodstream where it prevents HIV from multiplying.

Neither oral PrEP nor injectable PrEP (LEN) has to be taken for the rest of your life, only for as long as you feel you need it.

Both oral PrEP and injectable PrEP (LEN) can be used during pregnancy and breastfeeding. It protects both mother and baby from getting HIV.

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Appendix 6: Job Aid 6: Lenacapavir counselling guide for clinicians

Counselling guide for CLINICIANS

Job Aid 6

FRONT

PrEP (Pre-Exposure Prophylaxis) Initiation Counselling Guide for Clinicians

Step 1: If your client is interested in PrEP and has tested negative for HIV, inform them that the following health checks will have to be completed, depending on the method they choose:

Oral PrEP	Injectable PrEP
Over 15 years old and weigh 30kg or more	Weigh 35kg or more
Negative HIV test result	Negative HIV test result
No signs of HIV infection	No signs of HIV infection
Kidney function (blood) test if you are diabetic, hypertensive, 50 years and older, or pregnant	No blood test required

If all of these tests/checks are OK, the client could start PrEP immediately. You do not have to wait for the blood results to start PrEP.

Step 2: Explain the process of Starting PrEP to your client:

Starting Oral PrEP...

When you start using oral PrEP for the first time, you will:

Receive 1 container of oral PrEP with 28 pills

Day 1 → 28 Pills

Start by taking a pill a day, everyday

How soon does it start working?

Day 7

Oral PrEP starts working after 7 days of consistent use. Thereafter oral PrEP must be taken every day to prevent HIV.

Set a cellphone reminder to help you take your pill every day.

Every day

Return to the clinic after 1 month for an HIV test and check-up, and receive 3 containers of oral PrEP

Day 28 or sooner →

Return to the clinic every 3 months for an HIV test and check-up, and receive 3 containers of oral PrEP

3 Months → Every 3 months

Starting LEN...

When you start using LEN for the first time, you will:

Receive 2 injections and 2 pills

Day 1 → + +

Receive 2 pills to take home, to be taken the next day

Day 2 →

IMPORTANT: The two tablets that you take on day 1 and day 2, must be taken 24 hours apart, not sooner and not later!

Set a reminder!

How soon does it start working?

Day 3

LEN starts working on DAY 3 if you received the injection and taken 2 tablets on day 1, and 2 tablets on day 2.

Return to the clinic after 1 month for an HIV test and check-up

1 Month → HIV +

Return to the clinic every six months for 2 injections

6 Months → Every 6 months

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Counselling guide for CLINICIANS

Job Aid 6

BACK

(Continued)

Step 3: Provide the correct information and education about PrEP:

Oral PrEP

- Take a pill a day, every day.
- **Oral PrEP starts working after taking one a pill a day for 7 days.**
- Use additional protection such as condoms, or abstain from sex.
- If used correctly, PrEP prevents HIV by more than 90%.
- PrEP works best if you take one pill a day, every day!
- You can stop taking PrEP if you feel you no longer need it.
- If you want to stop PrEP, continue to take the pills for 7 days after your last sexual contact.

Injectable PrEP (LEN)

- Day 1: 2 injections and 2 tablets
  Day 2: 2 tablets
  Day 3: **LEN starts working**
- Use additional protection such as condoms, or abstain from sex on days 1 and 2.
- Return to the clinic every 6 months for your follow-up injections.
- LEN prevents HIV by more than 96%.
- You can stop using LEN if you feel you no longer need it.
- LEN will only prevent HIV for 28 weeks after your last injection.
- If you do not receive your LEN injection after 28 weeks, you are no longer protected.
- Return for a follow-up LEN injection or use a condom, or oral PrEP if you still need to prevent HIV.

Step 4: Provide support for continuation (pill-taking and follow-up clinic visits)

Oral PrEP

- Remember to take PrEP every day.
- PrEP tablets can be taken any time of day, with food or without food.
- If you forget to take a tablet, take it as soon as you remember - if more than 2 days have passed, contact your healthcare provider for guidance.

Injectable PrEP (LEN)

- It is **important** to remember to take your 2 tablets on day 2 after the injections - without these tablets, LEN is not effective.

REASSURE your client!

- PrEP is safe even if you are taking hormonal contraceptives, sex hormones or non-prescription drugs.
- PrEP is safe with alcohol, as long as it does not cause a person to forget to take their daily pill.

REMIND your client!

- It doesn't matter which method you choose, you will have to return to the clinic for follow-up visits, the nurse will tell you exactly when!
- Remember to take your pill(s) and return to the clinic, set an alarm or cellphone reminder.
- Link the date of your follow-up visit with another important event in your life, like your friend's birthday or even a public holiday... or set a reminder on your phone!

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Appendix 7: Job Aid 7: Lenacapavir fact sheet for clients

Lenacapavir fact sheet for clients

Job Aid 7

FRONT

PrEP

all about LENACAPAVIR

Lenacapavir = LEN

LEN is a 6-monthly HIV prevention option; when used as prescribed, it is **more than 96% effective** in preventing HIV.

More about the LEN injection:

- LEN is six-monthly injections given to prevent HIV.
- LEN is safe to use!
- LEN contains an antiretroviral ingredient called lenacapavir which is injected just under the skin on the stomach area or buttocks.

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HIV prevention choices

LEN is an additional HIV prevention option.

- Condoms
- HIV testing
- PrEP (LEN and oral PrEP)
- PEP
- STI management
- Male medical circumcision
- ART for people living with HIV

There are many ways to prevent HIV, we call this combination prevention. Speak to your healthcare provider to find out what is available and choose according to your needs.

WHO CAN USE LEN?
Any person who has an HIV-negative test result and weighs 35kg or more.

What is the difference between PrEP, PEP, and ART?

All three use antiretrovirals in different combinations for the following purposes:

- **PrEP** is when ARVs are taken **before** exposure to HIV, to **prevent** getting HIV
- **PEP** is when ARVs are taken **after** exposure to HIV, to **prevent** HIV (within 72 hours and taken for 28 days only)
- **ART** is when ARVs are used to treat a person living with HIV, and is taken lifelong

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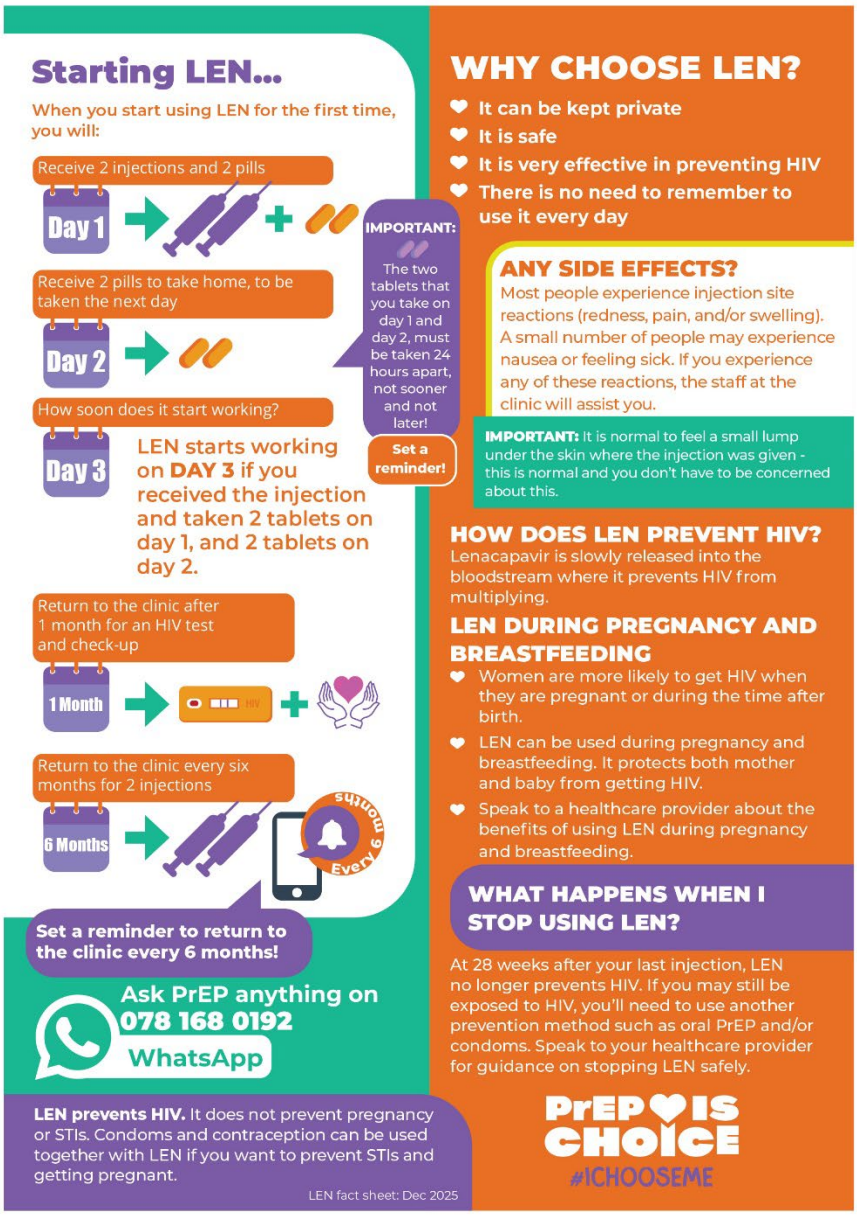
Lenacapavir fact sheet for clients

Job Aid 7

BACK

(Continued)



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Appendix 8: PrEP Clinical Form

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PrEP Clinical form (Initiation)

First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy **Gender:** M / F / TG	Address	
ID Number	**Client category** SW / MSM / TG		

Instructions: Please use the below form to capture initiation, continuation, discontinuation, and re-initiation for **ALL** PrEP methods: Oral PrEP (TDF/FTC), Lenacapavir (LEN) Cabotegravir (CAB), and Dapivirine viginal ring (DVR). If a client discontinues PrEP, continue the record with the corresponding date of discontinuation (section B). Should a client re-start or switch to another PrEP method, record with the corresponding date and PrEP method (section A), and all subsequent visits will be captured on this same form (section B). Additional clinical notes can be captured further below.

SECTION A: PrEP Initiation/Re-Initiation or Change of PrEP method

Date of Visit	HIV Test Result	PrEP Counselling Conducted?	PrEP Baseline Assessments					
			Weight (kg)	Pregnancy	Hepatitis B	STI Screening	Creatinine (eGFR/sCr)	PrEP method (*select one*):
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR
/ /	+ / -	Y / N		+ / - / NA		+ / -		TDF/FTC:LEN:CAB:DVR

Original PrEP Initiation Date	/ /

Transfer in:	
Date: / /	Clinic:

SECTION B: PrEP continuation, monitoring and discontinuation

# of months on PrEP	Next visit date:	Actual visit date:	PrEP Method (*TDF/FTC, LEN*)	Test results (if applicable)							
				HIV Test	Breast feeding	Weight (kg)	STI Screen	Pregnancy	Creatinine (eGFR/sCr)	Outcome (RIP, LTF, TFO, Sero, DNA, Disc)	Date of Outcome
0	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
1	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
2	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
3	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
4	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
5	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
6	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
7	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
8	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
9	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
10	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
11	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
12	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
13	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
14	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /

Notes: Medical history/reason for discontinuation or change of PrEP method etc.

NB: Please affix any copies of additional notes or laboratory results that are necessary.

PrEP Clinical form

First name	
Surname	
DOB	dd / mm / yy **Gender:** M / F / TG
ID Number	

History:

Signature: _____ Date: _____

Name: _____

PrEP Clinical form (Continuation)

First name	
Surname	
DOB	dd / mm / yy **Gender:** M / F / TG
ID Number	

SECTION B: PrEP continuation, monitoring and discontinuation

Original PrEP Initiation Date	/ /	Transfer In:	Date / /

# of months on PrEP	Next visit date:	Actual visit date:	PrEP Method *(TDF/FTC, LEN)*	Test results (if applicable)							
				HIV Test	Breast feeding	Weight (kg)	STI Screen	Pregnancy	Creatinine (eGFR/sCr)	Outcome (RIP, LTF, TFO, Sero, DNA, Disc)	Date of Outcome
15	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
16	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
17	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
18	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
19	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
20	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
21	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
22	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
23	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
24	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
25	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
26	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
27	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
28	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
29	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
30	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
31	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
32	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
33	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
34	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
35	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
36	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
37	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
38	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
39	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
40	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /

Notes: Medical history/reason for discontinuation or change of PrEP method

PrEP Clinical form

First name	
Surname	
DOB	dd / mm / yy **Gender:** M / F / TG
ID Number	

SECTION B: PrEP continuation, monitoring and discontinuation

Original PrEP Initiation Date	/ /	**Transfer In:**	**Date** / /

# of months on PrEP	**Next visit date:**	**Actual visit date:**	**PrEP Method** *(TDF/FTC, DVR, CAB)*	**Test results (if applicable)**							
				HIV Test	**Breast feeding**	**Weight** (kg)	**STI Screen**	**Pregnancy**	**Creatinine** (eGFR/sCr)	**Outcome** (RIP, LTF, TFO, Sero, DNA, Disc)	**Date of Outcome**
41	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
42	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
43	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
44	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
45	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
46	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
47	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
48	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
49	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
50	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
51	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
52	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
53	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
54	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
55	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
56	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
57	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
58	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
59	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
60	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
61	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
62	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
63	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
64	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
65	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /
66	/ /	/ /	TDF/FTC:LEN:CAB:DVR	+ / -	Y / N		+ / -	+ / - / NA			/ /

Notes: Medical history/reason for discontinuation or change of PrEP method etc.

Appendix 9: PrEP Pregnancy Outcome Form

PrEP Pregnancy Outcome Form

First name		Folder #	
Surname		Phone #	
DOB	dd / mm / yy **Gender:** M / F / TG	Address	
ID Number			

Instructions: Please use the below to capture the pregnacy outcome of mothers exposed to PrEP drugs at any time during their pregnancy. The available fields must be completed as much as possible with the relevant information available at the time of reporting. Please affix a copy of the PrEP clinical form and/or any relevant documentation.

PrEP drugs exposure before/during pregnancy

PrEP start date	dd / mm / yy	**Time of PrEP initiation**	☐ **Before pregnancy**	**Date of positive urine test**	dd / mm / yy
PrEP stop date	dd / mm / yy		☐ **During pregnancy**	**Estimated date of delivery**	dd / mm / yy

Drug name (s): _____ **Dose:** Daily ☐ Monthly ☐ Other ☐ Specify: _____

Pregnancy outcome

1. Did the client experience any complication during pregnancy?	Y **Yes. Specify:** N **No**
2. Did the client give birth to (a) live infant(s)?	Y **Yes. Date of delivery** dd / mm / yy N **No. Specify reason:**
3. Was the infant normal at birth?	Y **Yes** N **No. Specify abnormality and reason:**
4. Additional comment on pregnancy/delivery	

Infant (s) information

Infant number	Infant sex	Infant length (cm)	Infant weight (g)	APGAR score	Comment
1	F ☐ M ☐				
2	F ☐ M ☐				
3	F ☐ M ☐				
Relevant medical history (with focus on relevant prior gynaecological/obsteric history)					

1

Appendix 10: PrEP Seroconversion Form

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First name				Folder #	
Surname				Phone #	
DOB	dd / mm / yy	Gender:	M / F / TG	Address	
ID Number		Date of visit:	dd / mm / yy		

Instructions: Please use the form to document the circumstances/factors/situations pertaining to the seroconversion of the PrEP client. The available fields should be completed with the relevant information available at the time of reporting. Please complete and affix a copy of the PrEP clinical form and/or any relevant documentation.

PrEP drugs exposure before positive HIV test

PrEP start date: dd / mm / yy **Date of HIV+ Test:** dd / mm / yy **Drug name (s):**

PrEP History

1. At the time of the positive test result, is the client still on PrEP?	Y Client is still on PrEP — Which PrEP method was used? Oral / DVR / CAB LA / Len N Client is still on PrEP — (Specify date when the last PrEP dose was taken): dd / mm / yy
2.1 In the last 3 months, has the client been taking/using oral PrEP effectively? 2.2 Has the client taken a lenacapavir or cabotegravir injections as per schedule?	**Oral PrEP:** 0 Never missed a dose; 1 Missed doses 1-6day; 2 Missed doses >7 Day **Lenacapavir:** 0 On scheduled date; 1 Missed injection 1-14 days; 2 Missed injection >14 Days **CAB LA:** 0 On schedued date; 1 Missed injection 1-28 days; 2 Missed injection > 1 month **Ring:** 0 Ring inserted on schedule; 1 No ring 1-28 days; 2 No Ring > 1 month
3. What is the clients partner/s HIV status?	1 Partner/s is HIV negative; 2 Partner/s is HIV positive; 3 Don't know partner/s HIV status
4. Did client use a condom with partner/s?	1 Always; 2 Sometimes; 3 Never
5. Additional comments on circumstances relating to the seroconversion:	

Resistance Testing Results

Date	Comments:
dd / mm / yy	
dd / mm / yy	
dd / mm / yy	
Relevant medical history	

1